1 Art. 14 para. 1 letter a^{bis} TPA

1.1 Can both known and new active substances be submitted according to Art. 14 para. 1 letter a^{bis} TPA?

The procedure according to Art. 14 para. 1 letter a^{bis} TPA can be applied both for new and known active substances. Combinations of several active substances are also possible.

1.2 What time limits apply to the procedure according to Art. 14 para. 1 letter a^{bis} TPA?

The time limits for the procedure according to Art. 14 para. 1 letter a^{bis} TPA are based on the application type (e.g. NA KAS, NA NAS or type II IE also possible). The time limits for the various application types are described in the Guidance document *Time limits for authorisation applications HMV4*.

1.3 Do the procedures according to Art. 14 para. 1 letter a^{bis} TPA apply only to synthetic products, or can e.g. biologics, herbal medicinal products, transplant products or vaccines also be submitted in these procedures?

There are no limitations to specific medicinal product categories.

1.4 Can an application that has been rejected by Swissmedic be resubmitted according to Art. 14 para. 1 letter a^{bis} TPA if all conditions are fulfilled?

yes

1.5 Can a medicinal product also be authorised according to Art. 14 para. 1 letter a^{bis} TPA as interchangeable with a Swiss comparator medicinal product?

No, the interchangeability is not checked by Swissmedic in the simplified procedure according to Art. 14 para. 1 letter a^{bis} TPA. A standard application for the authorisation of a known active substance without innovation is required for the examination of interchangeability.

1.6 What date is decisive for the calculation of the 10-year period in a Mutual Recognition Procedure? The authorisation date of the national authority or the MRP authorisation date (day 90)?

The authorisation date of the national reference authority to which the Information for healthcare professionals also refers is decisive.

1.7 Can all pharmaceutical forms be submitted, or are there restrictions?

There are no restrictions

1.8 Does the pharmaceutical form of the notified medicinal product have to be the same as that of the foreign comparator medicinal product?

The pharmaceutical forms may differ but, according to the latest scientific and technical findings, any difference in the pharmaceutical form should not be expected to result in a different evaluation of efficacy and safety.
In the event of differences in pharmaceutical form, Swissmedic accepts, in addition to the documentation required by Guidance document *Authorisation according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA HMV4*, bioequivalence studies in order to be able to evaluate the impact of the difference on efficacy and safety.

1.9 What requirements exists for modules 2.6 and 2.7?

In modules 2.6 and 2.7, Swissmedic expects a summary of the bibliographic data on non-clinical and clinical aspects. The selection criteria for the literature compilation (search strategy, list of searched databases, service providers) should also be presented in a transparent and comprehensible manner.

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1.10 If a revalidation of the manufacturing process and the analytical methods is required in connection with the updating of module 3, can this be implemented after authorisation? What post-approval commitments (PAC) are possible?

The documentation on quality must correspond to the latest scientific findings at the time of the authorisation application and must be complete. If the validation of the manufacturing process satisfies the currently valid requirements (Guideline on process validation for finished products - information and data to be provided in regulatory submissions, EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1,Corr.1), and if no changes have been made to the manufacturing process since the validation, then revalidation is not required. Any revalidation can be submitted at a later date as a condition, provided this is permitted by the above-mentioned Guideline (for a standard process). The analytical methods must be validated according to the ICH requirements at the time of submission.

1.11 Can study reports also be submitted instead of publications?
Revised in September 2021

Yes. Authorisation of a medicinal product according to Art. 14 para. 1 a^{bis} of the Therapeutic Products Act (TPA, SR 812.21) requires submission of documentation on pharmacological, toxicological and clinical studies according to Art. 4 and 5 of the Therapeutic Products Licensing Requirements Ordinance (TPLRO, SR 812.212.22) or Art. 8 and 11 TPLRO for veterinary medicinal products. This may be submitted in bibliographic form if sufficient proof of the safety and efficacy of the medicinal product is available in the published specialist literature. Based on accumulated experience, Swissmedic will now accept submission on the basis of study reports or EU dossiers instead of bibliographic documentation.

Irrespective of which documentation the application is based on, the evidence submitted by the applicant must be summarised in a scientifically sound way and, for example evaluated critically by means of expert statements. For human medicinal products, this may also be in the form of a non-clinical / clinical overview (Module 2.4 / 2.5), or an expert report or detailed and critical summaries (DACS) for veterinary medicinal products.

1.12 As regards the product information, according to Art. 17b TPLO, sections 4-16 of the Information for healthcare professionals and sections 3-9 of the Patient information should be taken over from the foreign product information texts. However, specimen text requirements apply in Switzerland to certain medicinal product groups (e.g. paracetamol or NSAID). Are these specimen texts used?

The wording of the foreign product information should be taken over as a matter of priority, according to Art. 17b para. 4 TPLO. However, the product information texts must be supplemented by safety-related fixed and specimen texts according to Swissmedic requirements if these exist.

1.13 When applying Art. 14 para. 1 letter a^{bis} TPA, can reference be made to several EU/EFTA comparator medicinal products with the same active substance?

The crucial factor is that the sections of the product information (IHP and PI) specified in Art. 17b TPLO can be taken over only from a foreign comparator medicinal product. Comparability should be demonstrated between the medicinal product notified for authorisation and the comparator medicinal product whose product information texts are taken over.

1.14 Does the product information still need to be referenced when Article 14 para. 1 letter a^{bis} TPA is applied?

No

1.15 If the medicinal product has been authorised in several countries for more than 10 years, can all of these countries be listed on the packaging?

The requirements applicable to packaging are based on TPLRO. A list of countries in which the active substance is also authorised is not permitted.

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1.16 Can medicinal product combinations also be authorised according to Art. 14 para. 1 letter a^{bis} TPA?

Yes, medicinal product combinations can also be authorised according to Art. 14 para. 1 letter a^{bis} TPA. In this case the product information for the medicinal product combination is based on the comparator medicinal product sections specified in Art. 17b TPLO. In exceptional cases, Swissmedic will require the product information to be adapted to the Swiss requirements for safety-related aspects.

1.17 Can an application for the authorisation of a medicinal product combination according to Art. 14 para. 1 letter a^{bis} TPA be submitted if only the two monopreparations have been authorised in the EU/EFTA for over 10 years?

The key point is whether the active substance combination in a medicinal product combination has already been authorised for 10 years in the EU/EFTA.

1.18 Is it possible, for a medicinal product authorised according to Art. 14 para. 1 letter a^{bis} TPA, to request "new" indications based on new clinical, published studies as additional indications, if these indications are not authorised for the foreign comparator medicinal product on which the initial authorisation was based?

No.

1.19 Can the procedure according to Art. 14 para. 1 letter a^{bis} TPA be used not only for new authorisations but also for additional indications for medicinal products that are already authorised in Switzerland?

Art. 14 para. 1 letter a^{bis} TPA can also be used for additional indications, provided the medicinal product was already newly authorised according to Art. 14 para. 1 letter a^{bis} TPA. It should be noted that the sections of the product information (IHP and PI) specified in Art. 17b TPLO must be taken over from the same foreign comparator medicinal product. Mixing indications that are based on original documentation or indications that are based on a foreign comparator medicinal product are not permitted.

1.20 It is possible that an EU comparator medicinal product possesses OTC status but would be classified in Switzerland as a prescription-only medicine based on the indication, active substance, dosage strength or pack size.
In what dispensing category would such a medicinal product be classified in Switzerland?

Swissmedic maintains its practice in respect of dispensing categories and classifies products in dispensing categories based on the currently applicable criteria.

1.21 Under what variation category should an adaptation of the Swiss product information to the foreign comparator medicinal product be submitted? As a type IA or IB variation or type II variation?

This would involve a type IB variation (variation A.100)

1.22 Can variations in quality be submitted according to Art. 14 para. 1 letter a^{bis} TPA?

No.

1.23 What happens if the foreign comparator medicinal product is deleted (marketing reasons) or withdrawn (safety reasons)?

If the foreign comparator medicinal product is deleted in the reference country for marketing reasons, there will be no direct consequences for the authorisation status of the medicinal product authorised in Switzerland. The relevant note in the IHP / PI would probably be adapted to the new circumstances: "...is based on MEDICINAL PRODUCT NAME Y, which contains the same active substance(s) and has been authorised in COUNTRY Z for more than 10 years."

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If the foreign comparator medicinal product is withdrawn from the market for safety reasons, the corresponding safety signals must also be reported to Swissmedic (Art. 14a, para. 2 TPA). Furthermore, the authorisation holder is under an obligation to adapt the medicinal product information – continuously and without being prompted – in line with the state of the art in science and technology and with new events and assessments (Art. 28 TPO). If the authorisation holder does not withdraw the medicinal product voluntarily, Swissmedic would very probably initiate a review procedure and may well temporarily suspend the medicinal product.

1.24 Can document protection based on a bibliographic application in the procedure according to Art. 14 para. 1 letter a^{bis} TPA and still applicable in Switzerland be circumvented if this has already expired in the EU?

Yes. Since bibliographic documentation comprises published literature ("public knowledge") it is not subject to any document protection. Therefore, the applicant does not need to rely on protected documents (clinical study results) for a medicinal product authorised in Switzerland.

1.25 Can authorisations granted in the procedure according to Art 14 para. 1 letter a^{bis} TPA also serve as a basic authorisation for a co-marketing medicinal product?

Yes.

1.26 Is it essential for the chosen foreign comparator medicinal product to have been authorised in the EU/EFTA for at least 10 years? Revised in September 2021

No. It is sufficient to proof that, at the time of submission, the active substances have been authorised as a medicinal product in the indication applied for in an EU or EFTA country for at least 10 years.

1.27 Does the chosen foreign comparator medicinal product have to be authorised when the application is submitted?

Yes, the chosen comparator medicinal product must be authorised in the EU/EFTA when the application is submitted. However, if the foreign comparator medicinal product is withdrawn from the market at a later date for commercial reasons, the medicinal product authorised in Switzerland under Art. 14 para. 1 let. a^{bis} TPA can retain its authorisation provided the authorisation holder complies with all post-marketing obligations (see also 1.24).

1.28 Can an authorisation application for a KAS relate to a medicinal product (comparator medicinal product) that was authorised according to Art. 14 para. 1 a^{bis}?

No: according to Art. 12 TPLO para. 2, the comparator medicinal product must have been authorised on the basis of complete authorisation documents; in other words, all test results to which the KAS is supposed to refer must be contained in the documentation on the comparator medicinal product. In the Art. 14 para. 1 a^{bis} procedure, the documentation on preclinical and clinical efficacy and safety is only submitted in bibliographic form.

1.29 With regard to applications in accordance with Art 14 para. 1 letter a^{bis} TPA, will the United Kingdom still be deemed equivalent to an EU/EFTA country even after Brexit? Revised in December 2021

The UK has no longer been regarded as an EU/EFTA country since 1 January 2021. However, during a transitional period of five years, Swissmedic will continue to accept applications in accordance with Art. 14 para. 1 let. a^{bis} TPA that relate to 10-year authorisation of an active substance in the proposed indication in the UK. The authorisation of the active substance must have been granted before 1 January 2011. From 1 January 2026, this type of reference to a medicinal product authorised in the UK will no longer be permitted for new applications.

1.30 Should the date for the "Date of revision of the text XX.XXXX" in the fixed introductory text be revised with the update to the information for healthcare professionals and/or patient information under Art.14 para. 1 let. a^{bis} TPA? New in December 2021

No. The date refers to the first authorisation and should not be revised when updates are made.

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2 Art. 14 Duties. 1 letter a^{ter} TPA

2.1 Can both known and new active substances be submitted according to Art. 14 para. 1 letter a^{ter} TPA?

The procedure according to Art. 14 para. 1 letter a^{ter} TPA can be applied both for new and known active substances. Combinations of several active substances are also possible.

2.2 What time limits apply to the procedure according to Art. 14 para. 1 letter a^{ter} TPA?

The time limits for procedures according to Art. 14 para. 1 letter a^{ter} TPA are based on the application type (e.g. NA KAS, NA NAS or type II IE also possible). The time limits for the various application types are described in the Guidance document *Time limits for authorisation applications HMV4*.

2.3 Will cantonal authorisations still be possible?

Where the TPA exempts medicinal products from the obligation to be authorised (see Art. 9 para. 2 letter a-c^{bis} TPA), cantons may, within the scope of their powers, decide whether they wish to subject medicinal products to registration or reporting obligations.

2.4 For applications according to Art. 14 para. 1 letter a^{ter} TPA, can the requested pack sizes deviate from those of the foreign medicinal product if this is deemed to be appropriate?

Yes, deviations are possible if these accord with the dosage recommendation and the treatment regimen.

2.5 Under Art. 17c para. 1 TPLO, Information for healthcare professionals can be omitted from applications according to Art. 14 para. 1 let. a^{ter} TPA. Is it possible to produce Information for healthcare professionals on a voluntary basis so that this can be made available to the professionals concerned?

Yes, the company may use its own discretion to decide whether or not to issue Information for healthcare professionals.

2.6 Are "30 years of medical use in another country" and "15 years of medical use in the EU / EFTA" conditions that must be fulfilled cumulatively?

Yes.

2.7 What expectations does Swissmedic have relating to documentation on the therapeutic effect and the undesirable effects?

The requirements relating to the documentation for applications according to Art. 14 para.1 letter a^{ter} TPA vary considerably and depend on the therapy approach and the field of application. In order to clarify specific questions concerning documentation requirements, applicants can request Pre-Submission Advice from Swissmedic before submitting an application.

2.8 Are Modules 5 and 2.5 required?

Usually yes. The documentation on medical use, safety and the therapeutic effect should be submitted in Module 5. (Summary in Module 2.5)
A complete and updated Module 3 on quality must be submitted. Accordingly, Swissmedic also expects a complete Module 2.3 "Summary on pharmaceutical quality".

2.9 Can authorisations granted in the procedure according to Art 14 para. 1 letter a^{ter} TPA also serve as a basic authorisation for a co-marketing medicinal product?

yes

2.10 Can variations in quality be submitted according to Art. 14 para. 1 letter a^{ter} TPA?

No

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2.11 With regard to applications in accordance with Art 14 para. 1 letter a^{ter} TPA, will the United Kingdom still be deemed equivalent to an EU/EFTA country even after Brexit? New in December 2021

The UK has no longer been regarded as an EU/EFTA country since 1 January 2021. However, during a transitional period of 15 years, Swissmedic will continue to accept applications in accordance with Art. 14 para. 1 let. a^{ter} TPA with a foreign comparator product from the UK.

From 1 January 2036, foreign comparator products from the UK will no longer be permitted.

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3 Art. 14 para. 1 letter a^{quater} TPA

3.1 Can both known and new active substances be submitted according to Art. 14 para. 1 letter a^{quater} TPA?

The procedure according to Art. 14 para. 1 letter a^{quater} TPA can be applied both for new and known active substances. Combinations of several active substances are also possible.

3.2 What time limits apply to the procedure according to Art. 14 para. 1 letter a^{quater} TPA?

The time limits for procedures according to Art. 14 para. 1 letter a^{quater} TPA are based on the application type (e.g. NA KAS, NA NAS or type II IE also possible). The time limits for the various application types are described in the Guidance document *Time limits for authorisation applications HMV4*.

3.3 What expectations does Swissmedic have relating to documentation on the therapeutic effect and the undesirable effects?

The requirements relating to the documentation for applications according to Art. 14 para.1 letter a^{quater} TPA vary considerably and depend on the therapy approach and the field of application. In order to clarify specific questions concerning documentation requirements, applicants can request Pre-Submission Advice from Swissmedic before submitting an application.

3.4 Are Modules 5 and 2.5 required?

Usually yes. The documentation on medical use, safety and the therapeutic effect should be submitted in Module 5. The Summary in Module 2.5

A complete and updated Module 3 on quality must be submitted. Accordingly, Swissmedic also expects a complete Module 2.3 "Summary on pharmaceutical quality".

3.5 Is an "Information for healthcare professionals" for applications in the procedure according to Art. 14 para. 1 letter a^{quater} TPA merely "not necessary" or is it also "not permitted"? Revised in September 2021

In principle, Swissmedic does not check and approve any information for healthcare professionals when authorising a medicinal product according to Art. 14 para. 1 a^{quater}. However, the information for healthcare professionals can also be prepared at the applicant's discretion if this is beneficial for the safe use of the medicinal product.

3.6 Can authorisations granted in the procedure according to Art 14 para. 1 letter a^{quater} TPA also serve as a basic authorisation for a co-marketing medicinal product?

yes

3.7 Can variations in quality be submitted according to Art. 14 para. 1 letter a^{quater} TPA?

No

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